

particulate phase (a second phase). This description of two "phases" is a terminology employed to make clear that the claimed formulation contains two distinct solid domains, the inner solid domain or "phase" of polymer/drug particles, and an outer solid continuous domain or "phase" containing a second polymer and optionally other necessary pharmaceutical excipients.

WO 96/08243 does not describe or suggest the same construction. Rather, the formulations in WO 96/08243 are described as tablets with a core and an optional film coating. See, for instance, page 7 and Example 1. Moreover, the "hydrocolloid former" in WO 96/08243 is up to 15% by weight of the composition. (See page 6.) The film coating is in the range of 0.3-3.0% by weight. This clearly is not the same construction as the biphasic construction of the instant invention. In the instant invention, the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is more than about 30% (see claim 1 of the instant application) or 25 to 75% (see claim 43 of the instant application) by weight of the formulation.

Moreover, neither the art nor the rejection addresses limitations presented in the dependent claims. For example, claim 6 requires that the extended release material present in the inner solid particulate phase is different from the extended release material present in the outer solid continuous phase. Nowhere is this mentioned in the cited art or the rejection.

The secondary references do nothing to overcome the deficiencies of the primary reference. None of the secondary references suggest the construction claimed in the instant application. In fact, Chemical Abstract 126:229547, for example, relates to pellets.

Accordingly, for all these reasons, applicants request that this rejection be withdrawn.

Claims 1-33, 42-64 and 71 were also rejected under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse this rejection as well.

The claims were variously rejected under 35 U.S.C. §112, second paragraph. However, applicants believe that the claims are clear as written. For example, the rejection indicates that terms of improved physical properties and an expression of the layers and size relationships of particles should be included in the claims. Applicants believe that the scope of the claims is clear. They note that the limitations of claim 9, for instance, provides some of those terms suggested in the rejection. But applicants do not believe these limitations are necessary for understanding the scope of all of the claims.

With respect to the use of the terms "phase" and "biphasic", applicants point to the discussion above. Additionally, applicants point to the specification, for instance, on page 15, and to the examples. Applicants believe that the use of these terms is clear, especially in the context of the application.

Accordingly, applicants believe that this rejection should be withdrawn.

In view of the foregoing, reconsideration of this application, and allowance thereof with all the pending claims, are respectfully requested.

Respectfully submitted,

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